REMARKS

The above-identified Application has been carefully reviewed with the Office Action of March 24, 2009, the Examiner's comments, and the art references cited therein in mind. In response thereto, Applicants submit the following arguments in support of patentability. Favorable reconsideration is hereby respectfully requested.

Initially, the Applicants thank the Examiner for discussing the pending claims and the cited prior art with the Applicants' attorney by telephone on June 23, 2009. While no agreement was reached, the discussion was appreciated.

The independent claims are once again rejected as being unpatentable over Siddiqui in view of Sparkes under 35 U.S.C. § 103(a). This rationale is both incomplete and improper in view of the established standards for rejections under 35 U.S.C. § 103.

In this regard, the MPEP section 2141 states:

> The Supreme Court in KSR reaffirmed the familiar framework for determining obviousness as set forth in Graham v. John Deere Co. (383 U.S. 1, 148 USPQ 459 (1966))... As reiterated by the Supreme Court in KSR, the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:
>
> (A) Ascertaining the differences between the claimed invention and the prior art; and
>
> (B) Ascertaining the differences between the claimed invention and the prior art; and
>
> (C) Resolving the level of ordinary skill in the pertinent art.

In addition:

> When applying 35 U.S.C. 103, the following tenets of patent law must be adhered to:
>
> (A) The claimed invention must be considered as a whole;
>
> (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
>
> (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention and
>
> (D) Reasonable expectation of success is the standard with which obviousness is determined.

Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

As reflected above, the foregoing approach to obviousness determinations was recently confirmed by the United Stated Supreme Court decision in KSR INTERNATIONAL CO. V.

TELEFLEX INC. ET AL. 550 U.S. 1, 82 USPQ2d 1385, 1395-97 (2007), where the Court stated:

> In Graham v. John Deere Co. of Kansas City, 383 U. S. 1 (1966), the Court set out a framework for applying the statutory language of §103, language itself based on the logic of the earlier decision in Hotchkiss v. Greenwood, 11 How. 248 (1851), and its progeny. See 383 U. S., at 15–17. The analysis is objective:
>
> "Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." Id., at 17–18.

The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that '[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" (MPEP 2141). Simply stated, the Office Action has failed to at least (1) ascertain the differences between and prior art and the claims in issue; and (2) resolve the level of ordinary skill in the art. Furthermore, the alleged rationale for combining the references is merely an improper conclusory statement that embodies clear and improper hindsight rationale.

The Examiner's approach for assessing patentability is an *ex post facto* approach and Applicants maintain their previous arguments, especially those set forth in the response dated April 30, 2008. Furthermore, Applicants believe that they should address one by one all the allegations recited by the Examiner in the *"Response to Arguments"* section as follows:

1) First, a preliminary remark: Applicants are very surprised that the arguments of the Examiner in the *"Response to Arguments"* section of this 6th Office Action are identical to those mentioned in the 4th Office Action, despite the detailed arguments and amendments filed in response to the 4th and 5th Office Actions

Therefore, Applicants are in a difficult and unfair position because they have to respond to a communication made final although Applicants do not know why their arguments in response to the *"Response to Arguments"* section of the previous 4th Office Action were not even addressed. There are significant reasons why the cited combination of references is inappropriate in this case.

2) According to the Examiner, a prior art reference must either:

(i) be in the field of applicant's endeavor

(ii) or, if not, then be reasonably pertinent to the particular problem with which the applicant was concemed, in order to be relied upon as a basis for rejection.

For the reasons already set forth in a detailed manner in the response to the 4th Office Action, Sparkes is clearly not in the field of applicant's endeavor, since it relates to a wood screw. Therefore, above-mentioned condition (i) is not fulfilled. This seems to be acknowledged, at least implicitly, by the Examiner, who does not rely on this first condition in the rest of his argumentation. However the Examiner relies on above-mentioned condition (ii) in the rest of his argumentation, since he asserts that *"given the problem to be solved, which is incorporating a helical groove in a screw ..".*

However, it should be once again strongly pointed out that the manner the Examiner formulates the problem to be solved results from the inadmissible use of hindsight knowledge, because the helical shape is a part of the solution to the problem.

On the contrary, the technical problem addressed by an invention must be formulated in such a way that it does not contain pointers to the solution or partially anticipate the solution, even partially, since including part of a solution offered by an invention in the statement of the problem necessarily had to result in an *ex post facto* view being taken of inventive step when the state of the art was assessed in terms of that problem. In other words, and as already mentioned in one of their previous responses to the Office Action, if the problem is so formulated as to contain the solution, the solution is necessarily obvious (Problem: incorporating an helical groove / *"Obvious"* solution to this problem: incorporating an helical groove!).

Actually, the objective problem with which the applicant was concerned was to provide a compression screw for small bones fragments that is very *"aggressive"* but also resistant. Applicants believe that Sparkes is not *"reasonably pertinent"* to this particular problem, as required by above-mentioned condition (ii) because:

- Sparkes does not address the problem of compressing fragments, while the invention is directed to a compression screw used for coaptation of bone fragments in the step of: compressing said bone fragments together by the insertion and turning of said screw;

- Sparkes does not address the very specific problem of coaptation of small fragments, which implies the use of screws;

-Both the Applicants' screw and the screw of Siddiqui are self- tapping and designed to compress bone fragments by driving the screw into the bones to be secured. Therefore, why would one of ordinary skill in the art look to Sparkes?

- Sparkes is not concerned by aggressiveness or resistance issues; actually, the flute 14 is given a spiral shape only for conveying the wood cuttings to the surface of the wood (cf. col. 1, line 67 to col. 2, line 30 and claim 1, last lines). In fact, Sparkes, in Col. 2, lines 8-10, Sparkes recites "wood screw 10 readily drills a pilot hole for itself, and the wood cuttings 20 are conveyed upwardly as indicated by arrow 21 in Fig. 2. Further in Col. 2, lines 24-29, Sparkes recites "This angle should be about 30 degrees to properly convey the wood cuttings from the pilot hole drilled by the screw, itself. The angle should not be so great as to tend to drive the wood screw into the wood, but a certain amount of spiral is appropriate to assist in conveying the wood cuttings upwardly." Why is this done? The answer is in Col. 2, lines 57-62, where Sparkes recites, "The wood cuttings in the long spiral tend to be compressed and create an exceptionally strong fastening quality of the screw in the wood. The spiral flute through the threads act as a tap, cutting clean threads in the wood rather than compressing and splitting and weakening the material." The screw of Sparkes is quite obviously meant to be left in place. The wood would not stay together after removal of the screw. Sparkes contains absolutely no indication as to the potential effect of a spiral shape concerning the resistance of the screw, only that it is designed to, in effect, "cement" the screw in place. (Emphasis added). Compressing the removed wood cuttings and compressing the material are completely different.

Therefore, there is definitively no objective reason for considering that Sparkes is reasonably pertinent to the particular problem with which the Applicant was concerned.

Hence, above-cited condition (ii) is not fulfilled.

3) According to the Examiner, any need or problem known in the screw field and addressed by the patents can provide a reason for combining the elements in the manner claimed.

In other words, if Applicants understood correctly the Examiner's reasoning, the simple fact that Sparkes discloses the problem of conveying the wood cuttings to the surface of the wood, even if it has nothing in common with the real objective problem faced by the person skilled in the art, would have prompted the latter to adopt spiral-shaped grooves as taught by Sparkes. This reasoning is improper for assessing inventive step, because it is based on the very artificial premise that the skilled person is just looking for a way of modifying Siddiqui's screw, without any particular objective, only for the pleasure of modifying Siddiqui's screw, and choose to implement spiral-shaped flutes for conveying the wood cuttings to the surface, although he has absolutely no specific interest for such a technical function.

Such reasoning does not do justice to the invention, since in real life the skilled person searches in the prior art (more than 3000 published documents dealing with auto-tapping screws at the priority date of the instant application) with a specific technical objective in mind, which is, in the present case: improving the aggressiveness of a compression screw without harming the mechanical resistance of said screw.

With such an objective in mind, no doubt that the skilled person would not have considered Sparkes.

Furthermore, even if Applicants follow the Examiner's reasoning, it would not lead to the invention because of the following reasons:

- *"Any need or problem known in the screw field and addressed by the patents can provide a reason for combining...":* in Sparkes, said *"problem which can provide a reason for combining"* is the problem of conveving the wood cuttings to the surface.

- Therefore, assuming arguendo that the skilled person modifies Siddiqui's screw with an helical screw, he/she would necessarily provide Siddiqui's screw with helical flutes extending the full length of the screw, on purpose to convey the wood cuttings to the surface.

Not providing the intermediate portion with a flute would prevent the wood cuttings cut by the distal portion to be conveyed to the surface, which goes against the teaching of Sparkes and the alleged *"reason for combining".*

In other words, implementing the helical flute of Sparkes in the screw of Siddiqui would inevitably lead to a screw which differs from the invention since its intermediate portion would not be smooth but would be equipped with a flute.

4) According to the Examiner, *"regardless of Spakes primary purpose, it provides an obvious example of a screw with an helical groove and the prior art was replete with patents indicating that such a helical groove was ideal for a medical device (Carchidi et al)".*

This is clearly a non objective presentation of the prior art.

Actually, it should be strongly pointed out that:

- on one hand the helical grooves of Carchidi's screw (which is not a compression screw) are extremely <u>short,</u> since it covers only the first couple of threads (see fig. 1 and col. 2, line 46);

- on the other hand the prior art compression screws (such as Siddiqui's screw) have grooves.

Therefore, the real picture of the prior art is that:

- helical grooves are sometimes used for medical devices (they are not *"ideal");*

- grooves are ideal for medical screws, especially for compression screws.

5) According to the Examiner, *"where there is a design need or market pressure to solve a problem and there are a infinite number of identified, procedural solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. The proper question was whether a bone screw device designer of ordinary skill in the art facing the wide range of needs created by the developments in the screw fields, would have seen an obvious benefit to upgrading Siddiqui with an helical groove?"*

Regarding the question of whether the skilled person *"would have seen an obvious benefit to upgrading Siddiqui with an helical groove* ", it should be pointed out that Sparkes is much older than Siddiqui and that according to Sparkes (see col. 1, lines 10-12) the addition of a spiral flute is known at *"a very early time".*

Therefore, the addition of a spiral flute known for decades is clearly not an *"upgrading"* of the Siddiqui's screw. Thus, providing Siddiqui's screw with a long spiral flute goes clearly against the developments in the screw fields, contrary to the Examiner's opinion.

Furthermore, the only obvious benefit associated with the addition of a spiral flute is the conveying of wood cuttings to the surface. However, as explained above, this obvious benefit cannot be reached if the spiral flute does not extend the full length of the screw, including the intermediate portion, which goes against the teaching of the invention as claimed.

6) According to the Examiner, Sparkes taught of a screw with a helical groove, to have (i) easy starting ability and (ii) to facilitate counter-sinking, and also (iii) reducing the danger of splitting the material being used. The designer, accordingly, would follow the teaching of Sparkes.

The presentation of the teaching of Sparkes made by the Examiner is not technically correct.

Actually, the teaching of Sparkes can be objectively broken down into the following sub-teachings:

- Providing the tip of the screw with two flutes which begin at the point of the screw and are about the same shape so that the tip is symmetrical. This technical feature provides the easy starting ability (see col. 1, lines 34-37);

- Providing the head 24 with cutting grooves. This technical feature facilitates counter-sinking (see col. 2, limes 39-41);

- Providing the screw with flutes acting as a tap, cutting clean threads in the wood. This technical feature allows to reduce the danger of splitting the wood (see col. 2, lines 59-62).

In other words, all the advantages (i), (ii) and (iii) above do not objectively result from the spiral shape of the groove. This means that said advantages could be obtained with straight grooves.

The only technical effect provides by this spiral shape is the ability of conveying the wood cuttings to the surface, out of the hole (cf. col. 2, limes 28-30: " ... *a certain amount of spiral is appropriate to assist in conveying the wood cuttings upwardly"* and claim 1: *"...the first spiral flute carries wood dust out of the hole").*

Therefore, if the designer follows the teaching of Sparkes (although he has no objective reason to do so) he will provides Siddiqui's screw with helical flutes extending the whole length of the screw, including the intermediate smooth portion, on purpose to convey the wood cuttings upwardly.

7) According to the Examiner, Applicants haves not shown anything in the prior art that taught away from the use of Sparkes, not any secondary factors to dislodge the determination that at least claim 1 is obvious. Applicants disagree for the following reasons:

- Applicants have explained in the response to the 4th & 5th Office Actions that the presence of bone cuttings in the fracture zone must be proscribed because this cutting material is likely to prevent the bringing together and the perfect maintaining of the bone fragments. This is clearly stated in page 1, lines 26-29 of prior art document FR27873 13 (copy enclosed), published in 2000: *"L'emploi de vis induit également un risque d'arrachement et de refoulement de matière osseuse au niveau de la zone de fracture, cette matière venant ensuite s'opposer au rapprochement et au parfait maintien des fragments en contact mutual"*) which can be translated as follows: *"using screws generates a risk of wrenching and of driving back bony matter at the fracture zone, said bony matter preventing the bringing together and the perfect maintaining of the bone fragments".*

Therefore, on account of this technical prejudice, the skilled person would have been deterred from following the teaching of Sparkes.

- Although spiral flutes are known for decades, as acknowledged by Sparkes (col. 1, lines 10-I2), it should be noted that they were never implemented on compression

screws. Applicants believe this constitutes a secondary factor to dislodge the determination that the claims are obvious.

8) The Examiner relies on the Sakraida v. AG Pro case, in which the court came to the conclusion that when a patent *"simply arranges old elements with each performing the same function it had been known to perform"* and yields no more than one would expect from such arrangements, the combination is proper.

However, it should be once again strongly pointed out that the only function spiral flutes are known to perform is conveying the bone cuttings to the surface. This function can be performed only if the spiral flute extends over the intermediate portion of the screw. Therefore, the claimed invention does not simply arrange old elements with each performing the same function, since the helical grooves of the invention cannot perform the known function of conveying the bone cuttings to the surface, because they do not extend over the entire length of the screw.

9) Finally, the Examiner brought to Applicants' attention that only the flutes or grooves of Siddiqui are being replaced with the helical grooves of Sparkes, therefore, the smooth intermediate portion of Siddiqui would be devoid of flutes or grooves. The decision of replacing only the flutes or grooves of Siddiqui with the helical grooves of Sparkes implies clearly an inventive step, because it inhibits the known function of the spiral shape, namely conveying the wood dust out of the hole, to the surface.

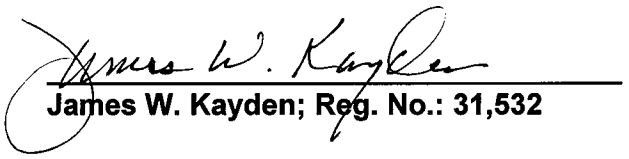
A person skilled in the art without inventive ability would implement an helical flute extending the whole length of the screw, including the intermediate smooth portion, for obtaining the conveying function (although the skilled person has no objective reason for seeking this function - see for example paragraph 7 above).

Furthermore, even if, according to the *ex post facto* approach of the Examiner, the straight grooves of Siddiqui are replaced by the helical grooves of Sparkes, one cannot arrive at the invention as claimed, but rather to a screw with short helical grooves, while the invention is directed to a screw with a distal helical groove extending substantially over the entire axial length of the thread of the distal portion.

CONCLUSION

With the amendments presented herein, it is believed that all the claims remaining in the Application are in condition for allowance. Early and favorable action in this regarding is hereby respectfully requested. Should there be any minor informalities remaining, the Examiner is respectfully requested to call the undersigned attorney so that this case may be passed to issue at an early date.

Respectfully submitted,



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